HFA-305
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

5052

Lachman Consultant Services
Attention: Robert Pollock
1600 Stewart Avenue
Westbury, NY 11590

AUG - 6 2002

Docket No.01P-0524/CP1

Dear Mr. Pollock:

This is in response to your petition filed on November 20, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Hydrocodone Bitartrate and Acetaminophen Oral Solution 10 mg/ 300 mg per 15 mL. The listed drug product to which you refer in your petition is Lortab® (Hydrocodone Bitartrate and Acetaminophen) Oral Solution, 7.5 mg/500 mg per 15 mL approved under ANDA 81-051 held by Mikart, Inc.

Your request involves a change in strength for the acetaminophen component from that of the listed drug products (i.e., from acetaminophen 500 mg to acetaminophen 300 mg) and a change in strength for the hydrocodone bitartrate component (i.e. from 7.5 mg to 10 mg). The changes you request are the type of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a strength that differs from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The FDA finds that the change in the strength of the acetaminophen component for the specific proposed drug product does not pose questions of safety or effectiveness because the proposed strength of the acetaminophen component falls within acceptable limits established by the Food and Drug Administration (FDA). The FDA has approved other products, which contain 300 mg of acetaminophen in combination with an opioid analgesic, and the uses and route of administration of the proposed drug product are the same as that of the listed drug product. In addition, the FDA finds that the change in the strength of the hydrocodone bitartrate component for the specific proposed drug product does not pose questions of safety or effectiveness because the proposed strength of the hydrocodone component falls within acceptable limits established by the Food and Drug Administration (FDA). The FDA has approved other products, which contain 10 mg of hydrocodone bitartrate in combination with an analgesic, and the uses and route

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of administration of the proposed drug product are the same as that of the listed drug product. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

When an ANDA is submitted for your proposed drug product, the proposed labeling should reflect the maximum number of doses per day that can be administered for your proposed drug product. The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988). . In addition, the maximum single dose of acetaminophen may not exceed 1000 mg. With respect to hydrocodone bitartrate, the maximum single dose is 10 mg and the total daily dose may not exceed 60 mg. Please consult the Labeling Review Branch at (301) 827-5845 if you have any questions regarding the proposed labeling for the specific drug product.

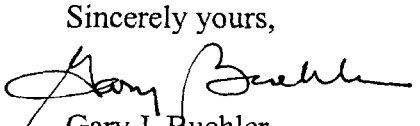
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for these drug products to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the drug product upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research